


IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,)	
)	
Plaintiff,)	
)	C.A. No. 21-1015 (LPS)
v.)	
)	
SAREPTA THERAPEUTICS, INC.,)	
)	REDACTED - PUBLIC VERSION
Defendant.)	

**SAREPTA'S OPENING BRIEF IN SUPPORT OF ITS MOTION TO STRIKE AND
TO DISMISS CLAIMS II-X OF NIPPON SHINYAKU'S COMPLAINT**

OF COUNSEL:

Charles E. Lipsey
J. Derek McCorquindale
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
1875 Explorer Street, Suite 800
Reston, VA 20190
(571) 203-2755

Michael J. Flibbert
Aaron Gleaton Clay
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001
(202) 408-4210

Alissa K. Lipton
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
Two Seaport Lane
Boston, MA 02210
(617) 646-1600

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Jack B. Blumenfeld (#1014)
Megan E. Dellinger (#5739)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
mdellinger@morrisnichols.com

*Attorneys for Defendant Sarepta
Therapeutics, Inc.*

Originally Filed: September 3, 2021
Redacted Version Filed: September 10, 2021

TABLE OF CONTENTS

	<u>Page</u>
I. NATURE AND STAGE OF PROCEEDINGS	1
II. SUMMARY OF ARGUMENT	2
III. STATEMENT OF FACTS	3
IV. ARGUMENT	5
A. LEGAL STANDARDS	5
1. Standing and Rule 12(b)(1) Standards for Declaratory Judgment Jurisdiction	5
2. Rule 12(f) Motion to Strike	6
3. Rule 12(b)(6) Standards	6
4. Rule 12(b)(7) and Rule 19 Requirements	7
B. THE COURT SHOULD STRIKE IMPROPER STATEMENTS UNDER RULE 12(F) AND DISMISS CLAIMS II AND III UNDER RULE 12(B)(1) FOR LACK OF SUBJECT MATTER JURISDICTION	8
C. CLAIM II SHOULD BE DISMISSED UNDER RULE 12(B)(6) FOR FAILURE TO STATE A CLAIM OF NONINFRINGEMENT	13
D. CLAIMS IV-X SHOULD BE DISMISSED UNDER RULE 12(B)(7) FOR FAILURE TO JOIN A PARTY PURSUANT TO RULE 19	16
V. CONCLUSION	20

TABLE OF AUTHORITIES

	<u>Page(s)</u>
 Cases	
<i>A123 Sys., Inc. v. Hydro-Quebec</i> , 626 F.3d 1213 (Fed. Cir. 2010).....	16, 17, 18, 19, 20
<i>Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc.</i> , 265 F.3d 1294 (Fed. Cir. 2001).....	11
<i>Ali v. Carnegie Inst. of Wash.</i> , 306 F.R.D. 20 (D.D.C. 2014).....	17, 19
<i>Ashcroft v. Iqbal</i> , 556 U.S. 662 (2009).....	6, 14
<i>Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office</i> , 689 F.3d 1303 (Fed. Cir. 2012).....	5
<i>Ballentine v. United States</i> , 486 F.3d 806 (3d Cir. 2007).....	6
<i>Becton, Dickinson & Co. v. NeuMoDx Molecular, Inc.</i> , C.A. No. 19-1126-LPS (D. Del. June 25, 2020).....	16
<i>Bell Atl. Corp. v. Twombly</i> , 550 U.S. 544 (2007).....	6, 14
<i>Comcast Cable Commc’ns, LLC v. OpenTV, Inc.</i> , 319 F.R.D. 269 (N.D. Cal. 2017).....	15
<i>Danisco U.S. Inc. v. Novozymes A/S</i> , 744 F.3d 1325 (Fed. Cir. 2014).....	5
<i>Delano Farms Co. v. Cal. Table Grape Comm’n</i> , 655 F.3d 1337 (Fed. Cir. 2011).....	17
<i>Fantasy, Inc. v. Fogerty</i> , 984 F.2d 1524 (9th Cir. 1993)	6
<i>Feriozzi Co. v. Ashworks, Inc.</i> , 130 F. App’x 535 (3d Cir. 2005)	7
<i>Gen. Refractories Co. v. First State Ins. Co.</i> , 500 F.3d 306 (3d Cir. 2007).....	7, 16

<i>Independent Wireless Tel. Co. v. Radio Corp.</i> , 269 U.S. 459 (1926).....	17, 19, 20
<i>Johnson v. AOL, Inc.</i> , 280 F. Supp. 2d 1018 (N.D. Cal. 2003)	12
<i>Lincoln Benefit Life. Co. v. AEI Life, LLC</i> , 800 F.3d 99 (3d Cir. 2015).....	5
<i>Lone Star Silicon Innovations LLC v. Nanya Tech.</i> , 925 F.3d 1225 (Fed. Cir. 2019).....	16, 17, 19
<i>Matthews Int’l Corp. v. Biosafe Eng’g</i> , LLC, 695 F.3d 1322, 1328 (Fed. Cir. 2012)	13
<i>MedImmune, Inc. v. Genentech, Inc.</i> , 549 U.S. 118 (2007).....	5
<i>Microsoft Corp. v. SynKloud Techs., LLC</i> , 484 F. Supp. 3d 171 (D. Del. 2020).....	13
<i>Morrow v. Microsoft Corp.</i> , 499 F.3d 1332 (Fed. Cir. 2007).....	17
<i>Morse v. Lower Merion Sch. Dist.</i> , 132 F.3d 902,906 (3d Cir. 1997).....	7, 12, 14
<i>Osteotech, Inc. v. Regeneration Techs., Inc.</i> , No. 3:06-cv-04249-FLW, 2008 WL 4449564 (D.N.J. Sept. 25, 2008)	9
<i>Pension Advisory Grp., Ltd. v. Cnty. Life Ins. Co.</i> , 771 F. Supp. 2d 680 (S.D. Tex. 2011)	11
<i>Perez v. Indian Harbor Ins. Co.</i> , ___ F. Supp. 3d ___, No. 4:19-cv-07288-YGR, 2020 WL 2322996 (N.D. Cal. May 11, 2020).....	11
<i>Pfizer Inc. v. Elan Pharm. Research Corp.</i> , 812 F. Supp. 1352 (D. Del. 1993).....	17, 18
<i>Philadelphia’s Church of Our Savior v. Concord Twp.</i> , No. 03-1766, 2004 WL 1824356 (E.D. Pa. July 27, 2004)	11
<i>Pilot Inc. v. Noco Co.</i> , No. CV-20-01452-PHX-SRB, 2021 WL 2188525 (D. Az. Feb. 12, 2021)	14, 15, 16
<i>Prasco, LLC v. Medicis Pharm. Corp.</i> , 537 F.3d 1329 (Fed. Cir. 2008).....	13

<i>Princeton Digital Image Corp. v. Konami Digital Entm't Inc.</i> , No. 12-1461-LPS-CJB, 2017 WL 239326 (D. Del. Jan. 1, 2017).....	3, 15, 16
<i>Provident Tradesmens Bank & Trust Co. v. Patterson</i> , 390 U.S. 102, 88 S. Ct. 733, 19 L. Ed. 2d 936 (1968).....	7
<i>SanDisk Corp. v. STMicroelectronics, Inc.</i> , 480 F.3d 1372 (Fed. Cir. 2007).....	2, 9, 10
<i>Schuylkill Energy Res., Inc. v. Penn. Power & Light Co.</i> , 113 F.3d 405 (3d Cir.1997).....	7, 12, 14
<i>Steel Co. v. Citizens for a Better Env't</i> , 523 U.S. 83 (1998).....	6
<i>Victor G. Reiling Assocs. Design Innovation, Inc. v. Fisher-Price, Inc.</i> , 407 F. Supp. 2d 401 (D. Conn. 2006).....	9
<i>Whitehead v. Gateway Chevrolet</i> , No. 03C5684, 2004 WL 316413 (N.D. Ill. Feb. 2, 2004).....	11
<i>Wilton v. Seven Falls Co.</i> , 515 U.S. 277 (1995).....	13

Federal Statutes

28 U.S.C. § 2201(a)	5
35 U.S.C. § 271(b)	16
35 U.S.C. § 271(c)	16

Rules

Delaware Rule of Evidence 408	9
Federal Rule of Evidence 408.....	9, 11
Fed. R. Civ. P. 8(a)	14
Fed. R. Civ. P. 12.....	<i>passim</i>
Fed. R. Civ. P. 12(b)(1).....	<i>passim</i>
Fed. R. Civ. P. 12(b)(6).....	<i>passim</i>
Fed. R. Civ. P. 12(b)(7).....	<i>passim</i>
Fed. R. Civ. P. 12(f).....	<i>passim</i>

Fed. R. Civ. P. 19..... *passim*

Fed. R. Civ. P. 19(a) *passim*

Fed. R. Civ. P. 19(b) *passim*

Fed. R. Civ. P. 19(c) *passim*

Other Authorities

Black’s Law Dictionary 1232 (9th ed. 2009).....18

5 Charles A. Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1382
 (1990).....6

Rutter Grp. Practice Guide Fed. Civil Procedure Before Trial (Nat’l Ed.) (2021)12

I. NATURE AND STAGE OF PROCEEDINGS

Plaintiff Nippon Shinyaku Co., Ltd. (“NS”) filed its ten-count Complaint against Defendant Sarepta Therapeutics, Inc. (“Sarepta”) on July 13, 2021. *See* D.I. 2. At the same time, NS also moved for a preliminary injunction concerning certain *inter partes* review (“IPR”) petitions filed by Sarepta. *See* D.I. 4-5. Briefing on that motion has been completed. *See* D.I. 5, 18, 25.

In Claim I, NS alleges that Sarepta [REDACTED] [REDACTED] because Sarepta filed its IPR petitions on June 21, 2021.¹ D.I. 2 at ¶¶ 1, 56-64. Sarepta opposed NS’s motion for preliminary injunction, [REDACTED] [REDACTED] and establishing that other factors support denial of a preliminary injunction. *See* D.I. 18.

In Claim II, NS seeks a declaratory judgment of noninfringement of three University of Western Australia (“UWA”) patents licensed to Sarepta, identifying NS’s VILTEPSO® product. D.I. 2 at ¶¶ 2, 65-67; *see infra* § IV.B.

In Claim III, NS seeks a declaratory judgment of invalidity with respect to the UWA Patents. D.I. 2 at ¶¶ 2, 68-74; *see infra* § IV.B.

In Claims IV-X, NS asserts that Sarepta infringes seven patents—“the NS Patents”²—issued to both NS and the National Center of Neurology and Psychiatry (“NCNP”) as assignees. *See* D.I. 2 at ¶¶ 75-147; *see also infra* § IV.D. The NS Patents are the subject of Sarepta’s IPR petitions.

¹ *Sarepta Therapeutics, Inc. v. Nippon Shinyaku Co., Ltd.*, IPR2021-01134; IPR2021-01135; IPR2021-01136; IPR2021-01137; IPR2021-01138; IPR2021-01139; IPR2021-01140.

² U.S. Patent Nos. 9,708,361 (Claim IV); 10,385,092 (Claim V); 10,407,461 (Claim VI); 10,487,106 (Claim VII); 10,647,741 (Claim VIII); 10,662,217 (Claim IX); 10,683,322 (Claim X).

Sarepta respectfully submits this brief in support of its motion under Federal Rules of Civil Procedure 12(b)(1), 12(b)(6), 12(b)(7), and 12(f) to strike and dismiss Claims II-X of NS's Complaint.

II. SUMMARY OF ARGUMENT

In its Complaint, [REDACTED] failing to articulate an actual case or controversy for this Court to decide. Various counts in the Complaint, moreover, do not satisfy the pleading standard set forth in *Iqbal/Twombly* and the Federal Rules of Civil Procedure, but instead simply track the elements of claims and lack factual support. For all these reasons, as further described below, Claims II through X of its Complaint must be dismissed.

1. *Claims II and III of the Complaint should be dismissed under Federal Rules of Civil Procedure 12(f) and 12(b)(1) for lack of subject matter jurisdiction and standing. See infra § IV.B.* NS relies on [REDACTED] to allege jurisdiction under the Declaratory Judgment Act. But these allegations should be stricken under Rule 12(f) for [REDACTED]

[REDACTED] The Federal Circuit has recognized that “[t]o avoid the risk of a declaratory judgment action,” parties may [REDACTED] *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1375 n.1 (Fed. Cir. 2007).

2. *Claim II of the Complaint should also be dismissed under Rule 12(b)(6) for failure to state a claim for declaratory judgment of noninfringement. See infra § IV.C.* The Complaint's statements regarding noninfringement are threadbare conclusions, lacking any factual support. D.I. 2 at ¶¶ 2, 67. Such bare assertions of noninfringement do not rise to the required level of plausibility. *Id.* (applying *Princeton Digital Image Corp. v. Konami Digital Entm't Inc.*, No. 12-1461-LPS-CJB, 2017 WL 239326, at *5 (D. Del. Jan. 19, 2017), where declaratory judgment allegations of noninfringement were dismissed for failure to satisfy notice pleading standards).

3. *Claims IV-X of the Complaint should be dismissed under Rule 12(b)(7) for failure to join an indispensable party under Rule 19. See infra § IV.D.* NS alleges that NCNP is an assignee and co-owner of the NS Patents, D.I. 2 at ¶¶ 28-37; however, NCNP, a necessary and indispensable party, is not joined in this action in which its patents are asserted against Sarepta. NCNP has recently affirmed that it has an ongoing interest with respect to the NS Patents, yet NS fails in the Complaint to adequately plead required facts related to this omitted entity under Rule 19. *See infra § IV.D.*

III. STATEMENT OF FACTS

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Further, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] and several weeks before NS filed this action in mid-July—Sarepta challenged the patentability of *NS's patents* before the USPTO; those

[REDACTED]

petitions remain pending.⁵ Sarepta did not, however, allege or pursue infringement by VILTEPSO[®] of the *UWA patents* in any court.

IV. ARGUMENT

A. LEGAL STANDARDS

1. Standing and Rule 12(b)(1) Standards for Declaratory Judgment Jurisdiction

Under the Declaratory Judgment Act, a “case of actual controversy” must exist to be justiciable in federal court. *See* 28 U.S.C. § 2201(a); *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 126-27 (2007). An Article III “case or controversy” exists when “the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” *MedImmune*, 549 U.S. at 127. In the context of an action for declaratory judgment of patent noninfringement or invalidity, jurisdiction may exist only where there is “an affirmative act by the patentee related to the enforcement of his patent rights.” *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1318 (Fed. Cir. 2012), *rev’d in part on other grounds sub nom. Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013). Plaintiff has the burden to prove an actual controversy exists under the Declaratory Judgment Act. *See Danisco U.S. Inc. v. Novozymes A/S*, 744 F.3d 1325, 1329 (Fed. Cir. 2014).

Motions brought under Rule 12(b)(1) may present either a facial or factual challenge to subject matter jurisdiction. *See Lincoln Benefit Life. Co. v. AEI Life, LLC*, 800 F.3d 99, 105 (3d Cir. 2015). In reviewing a *facial* challenge under Rule 12(b)(1), only matter within the four corners of the complaint or attached to it is considered—i.e., the standards relevant to Rule 12(b)(6) apply.

⁵ As explained, *see infra* § IV.D, NCNP is a co-patentee with NS on the seven NS Patents asserted in Claims IV-X.

Closely related, a motion to dismiss for lack of standing also may be brought under Rule 12(b)(1), because standing is a jurisdictional matter. *See Ballentine v. United States*, 486 F.3d 806, 810 (3d Cir. 2007). To satisfy the constitutional minimum for standing, the plaintiff must allege (1) an injury-in-fact (i.e., concrete and actual or imminent, not conjectural or hypothetical); (2) a fairly traceable connection to the defendant’s alleged conduct, and (3) that is redressable. *See Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 102-03 (1998).

2. Rule 12(f) Motion to Strike

Rule 12(f) provides that a court “may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter.” Fed. R. Civ. P. 12(f). Immaterial matter, for example, is “that which has no essential or important relationship to the claim for relief or the defenses being pleaded.” 5 Charles A. Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1382, at 706-07 (1990). Impertinent matter consists of “statements that do not pertain, and are not necessary, to the issues in question.” *Id.* at 711. A Rule 12(f) motion to strike avoids the time and expense of litigating spurious issues by dispensing with those issues before trial. *Fantasy, Inc. v. Fogerty*, 984 F.2d 1524, 1527-28 (9th Cir. 1993), *rev’d on other grounds*, 510 U.S. 517 (1994) (citation omitted) (affirming grant of motion to strike where allegations created serious risks of prejudice, delay, and confusion of issues). Grounds for a motion to strike must appear on the face of a pleading or from matters as to which courts may take judicial notice. *Id.*

3. Rule 12(b)(6) Standards

A complaint must contain sufficient facts, accepted as true, to state a claim to relief that is plausible on its face. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Further, a plaintiff’s obligation to provide the grounds of its entitlement to relief “requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Twombly*, 550 U.S. at 555. The Court is not obligated to accept as

true “bald assertions,” *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997), or “unsupported conclusions,” *Schuylkill Energy Resources, Inc. v. Pennsylvania Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997).

4. Rule 12(b)(7) and Rule 19 Requirements

Under Rule 12(b)(7), a party may seek dismissal of a complaint for failure to join a necessary and indispensable party under Rule 19. In deciding whether to grant such a dismissal, the Court must first determine whether the omitted party is a “necessary party” under Rule 19(a). *See Gen. Refractories Co. v. First State Ins. Co.*, 500 F.3d 306, 312 (3d Cir. 2007). A party is necessary if, in its absence, any of the following pertains: (1) complete relief cannot be afforded to the present parties, (2) the disposition of the action would impair the party’s ability to protect its own interest, or (3) any of the present parties would be subject to a substantial risk of multiple or inconsistent obligations. *See id.*; Fed. R. Civ. P. 19(a). If a party is necessary under Rule 19(a), it must be joined if feasible. If a party is not joined, the plaintiff “must state: (1) the name, if known, of any person who is required to be joined if feasible but is not joined; and (2) the reasons for not joining that person.” Fed. R. Civ. P. 19(c).

If joinder is necessary, but not feasible, the Court must determine whether the party is “indispensable” under Rule 19(b). This requires balancing the interests of the plaintiff, the defendant, the absent party, the courts, and the public. *See Feriozzi Co. v. Ashworks, Inc.*, 130 F. App’x 535, 538-39 (3d Cir. 2005) (citing *Provident Tradesmens Bank & Trust Co. v. Patterson*, 390 U.S. 102, 109-11 (1968)). If an absent party is indispensable, the Court must dismiss the action. *See Gen. Refractories*, 500 F.3d at 312.

B. THE COURT SHOULD STRIKE IMPROPER STATEMENTS UNDER RULE 12(F) AND DISMISS CLAIMS II AND III UNDER RULE 12(B)(1) FOR LACK OF SUBJECT MATTER JURISDICTION

Claims II and III seek declaratory judgments of noninfringement and invalidity of the UWA Patents. D.I. 2 at ¶¶ 2, 9, 11, 66-74. But NS seeks to establish its would-be declaratory judgment jurisdiction based [REDACTED]

[REDACTED]

[REDACTED]

D.I. 2 at ¶ 66 (Claim II); *id* at ¶ 69 (Claim III); *see also id.* at ¶ 11. These assertions fail to provide a basis for invoking the Declaratory Judgment Act. [REDACTED]

[REDACTED] paragraphs 11, 66, and 69 of the Complaint should be stricken in their entirety under Rule 12(f) as “impertinent” and “immaterial.” *See* Fed. R. Civ. P. 12(f).

On its face, the Complaint references [REDACTED]
[REDACTED] *See* D.I. 2 at ¶¶ 11, 66, 69 (three nearly identical allegations). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Id. (emphases added). Accordingly, [REDACTED] cannot serve as a proper basis for declaratory judgment jurisdiction because such [REDACTED]

[REDACTED] *See id.* Such use is also [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

In *SanDisk*, the Federal Circuit stated that “[t]o avoid the risk of a declaratory judgment action,” parties may [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

Sarepta and NS did just that. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] See D.I. 2

at ¶¶ 11, 66, 69.

Sarepta is prejudiced by NS's characterizations in the Complaint regarding the [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

As *SanDisk* recognized, [REDACTED] should prevent this harm to Sarepta [REDACTED]

[REDACTED] 480 F.3d at 1375 n.1. NS's declaratory judgment claims entangle the UWA patents in litigation, depriving Sarepta [REDACTED]

[REDACTED] See *id.*

NS cannot in this case rely on [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Nor can NS rely on [REDACTED] here in its claims for declaratory judgment regarding invalidity and noninfringement simply because their Complaint also includes [REDACTED] Rather, [REDACTED]

[REDACTED]

Striking NS's improper statements here pursuant to Rule 12(f) would promote "the policy in favor of protecting settlement negotiations from being admitted as evidence, thus serving to encourage settlements." *See Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc.*, 265 F.3d 1294, 1307-08 (Fed. Cir. 2001) (affirming district court's exclusion of settlement negotiation evidence proffered to prove inequitable conduct). Pursuant to the same policy, federal courts routinely strike portions of pleadings derived from [REDACTED] [REDACTED] *E.g., Philadelphia's Church of Our Savior v. Concord Twp.*, No. 03-1766, 2004 WL 1824356, at * 2 (E.D. Pa. July 27, 2004) ("While Rule 408 does not apply to pleadings directly, repeated decisions from this Court have held that allegations in a complaint may be stricken, under Rule 12(f), as violative of these policies.") (collecting cases); *see also, e.g.*, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]
 [REDACTED]
 [REDACTED]
 [REDACTED]

NS's Complaint offers three nearly identical paragraphs improperly rooted in alleged [REDACTED] to support declaratory judgment jurisdiction for Claims II and III. *See* D.I. 2 at ¶¶ 11, 66, 69. If the Court strikes these paragraphs pursuant to Rule 12(f), there would be no alleged facts left for the Court to consider and dismissal for lack of declaratory judgment subject matter jurisdiction should follow as a matter of law under Rule 12(b)(1) or Rule 12(b)(6).⁶

In any event, even if the Court declines to strike the paragraphs, they provide only “bald assertions” and “unsupported conclusions.” *Morse*, 132 F.3d at 906; *Schuylkill*, 113 F.3d at 417. NS's vaguely pleaded allegations [REDACTED] fail to provide sufficient notice of what facts are relied on to demonstrate declaratory judgment jurisdiction. *See* D.I. 2 at ¶¶ 11, 66, 69. NS has not pleaded that Sarepta created an immediate threat by its actions, nor could it—there was never a cease-and-desist letter nor any other specific infringement allegation identified. *See id.* In fact, immediately after [REDACTED] and three weeks before NS filed this action, Sarepta took action only to challenge NS's patents before the PTAB, not to allege or pursue infringement by VILTEPSO® of the UWA patents in district court. Had Sarepta intended to pursue a claim of infringement by VILTEPSO® of the UWA patents immediately after [REDACTED]

⁶ Coupling Rules 12(f) and other 12(b) grounds for this purpose is permitted. *See Rutter Grp. Practice Guide Fed. Civil Procedure Before Trial (Nat'l Ed.)*, at [9:372-9:372:1] (2021) (a pre-answer motion to strike joined with a motion to dismiss for failure to state a claim may eliminate one or more of claims).

At bottom, to determine “whether a justiciable controversy is present, the analysis must be calibrated to the particular facts of each case.” *Matthews Int’l Corp. v. Biosafe Eng’g, LLC*, 695 F.3d 1322, 1328 (Fed. Cir. 2012). In view of NS’s allegations in the Complaint [REDACTED] [REDACTED] and the insufficient pleading that follows, the Court should exercise its discretion to refuse declaratory judgment jurisdiction because none exists. *See Wilton v. Seven Falls Co.*, 515 U.S. 277, 288-89 (1995).

C. CLAIM II SHOULD BE DISMISSED UNDER RULE 12(B)(6) FOR FAILURE TO STATE A CLAIM OF NONINFRINGEMENT

Additionally, in determining whether declaratory judgment jurisdiction exists, the Court must look to the elements of the potential cause of action. *See Microsoft Corp. v. SynKloud Techs., LLC*, 484 F. Supp. 3d 171, 181 (D. Del. 2020). Here, NS fails to adequately plead any facts supporting its noninfringement claims. *See* D.I. 2 at ¶¶ 65-67.

NS has the burden in seeking declaratory judgment of noninfringement under Claim II to plead sufficient facts showing a plausible claim. *See Microsoft*, 484 F. Supp. 3d at 176. But NS does not satisfy the pleading standard of Rule 8(a) with its conclusory allegations:

2. These claims arise out of

⁷ Moreover, as explained above, *see supra* pp. 3-4 [REDACTED], NS has not alleged, and cannot allege, any cognizable injury-in-fact that is fairly traceable to *Sarepta*'s conduct given the [REDACTED] in order to show standing. "Absent an injury-in-fact fairly traceable to the patentee, there can be no immediate and real controversy." *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1338 (Fed. Cir. 2008).

[REDACTED]

67. Nippon Shinyaku denies infringing, inducing others to infringe, or contributing to the infringement of any claim of the UWA patents, either literally or under the doctrine of equivalents.

D.I. 2 at ¶¶ 2, 67. As the Supreme Court has instructed, “[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Iqbal*, 556 U.S. at 678; *Twombly*, 550 U.S. at 555. These assertions regarding Claim II do not rise to the level of plausibility and fail to provide Sarepta with notice of the basis of NS’s noninfringement claim. *See, e.g., Pilot Inc. v. Noco Co.*, No. CV-20-01452-PHX-SRB, 2021 WL 2188525, at *4 (D. Az. Feb. 12, 2021) (“Defendant’s assertion that it needed to only satisfy the jurisdictional requirements of the Declaratory Judgment Act . . . to properly plead noninfringement and invalidity is unsupported Defendant was required to plead its counterclaims in accordance with Rule 8, *Twombly*, and *Iqbal*. It failed to do so.”) (collecting cases).

NS’s statement regarding direct infringement in Claim II—i.e., that “*Nippon Shinyaku denies infringing . . . either literally or under the doctrine of equivalents*”—is facially deficient under the notice requirements of Rule 8(a). *See* D.I. 2 at ¶ 67. It is a mere denial. Even considering additional matter in paragraph 2—i.e., [REDACTED]

[REDACTED] this simply denies the elements of direct infringement. *See id.* at ¶ 2. NS’s conclusory allegations are “a formulaic recitation of the elements of a cause of action [and] will not do.” *Twombly*, 550 U.S. at 555. The Court rejects “bald assertions” and “unsupported conclusions” and should dismiss. *See Morse*, 132 F.3d at 906; *Schuylkill*, 113 F.3d at 417.

Notably, NS fails to even identify what activity it deems noninfringing. *See* D.I. 2 at ¶¶ 2, 65-67. The Complaint does not go beyond conclusory statements of noninfringement by pointing

to any specific facts regarding *how* NS's VILTEPSO® product does not meet one or more of the limitations of any claim of any UWA patent. *See Comcast Cable Commc'ns, LLC v. OpenTV, Inc.*, 319 F.R.D. 269, 273 (N.D. Cal. 2017) (dismissing noninfringement claim and holding that the “complaint must go beyond only stating in conclusory terms that each accused product or service meets the elements of non-infringement and must also set forth factual allegations showing *how* each accused product or service specifically does not meet at least one claim limitation”); *see also Princeton Digital*, 2017 WL 239326, at *5. Here, the Complaint fails to identify any particular UWA claims or NS activities giving rise to an actual controversy, D.I. 2 at ¶ 67, and effectively seeks an unbounded advisory opinion of noninfringement. *See Pilot*, 2021 WL 2188525, at *4.

The necessity of applying *Twombly/Iqbal* standards even to declaratory judgment claims of noninfringement is explained and illustrated in *Princeton Digital*, which involved similarly sparse noninfringement allegations:

29. Harmonix and EA have not infringed and are not infringing, either directly or indirectly, nor have the[y] contributed to or induced infringement by others, of any valid claim of the '129 patent, either literally or under the doctrine of equivalents.

30. Accordingly, Harmonix and EA are entitled to a declaratory judgment that they have not infringed and do not infringe the '129 patent.

2017 WL 239326, at *5. In granting a Rule 12(b)(6) motion to dismiss, the Court held that “Harmonix and EA do not seriously contend that . . . allegations that certain of their products do not meet the limitations of the relevant claims of the patent-in-suit[] are robust enough to meet the *Twombly/Iqbal* standard. And they are not.” *Id.* This was because the three paragraphs that made up the counterclaim contained “no facts of any kind, let alone sufficient facts to make out a plausible claim.” *Id.*; *accord Becton, Dickinson & Co. v. NeuMoDx Molecular, Inc.*, C.A. No. 19-

1126-LPS, D.I. 56, Tr. at 30:9-24 (D. Del. June 25, 2020) (“I am informed by, among other things, the *Princeton Digital* case that is cited in the briefing; and while I am certainly not requiring anything like the details one sees in an infringement or noninfringement claim chart, I do think that a defendant attempting to assert a counterclaim of noninfringement has to do more than just simply parrot the statute and say I don’t infringe, which is essentially all the defendant has done at this point.”).

NS’s allegations here are similarly threadbare (“Nippon Shinyaku denies infringing ... any claim of the UWA patents”) and thus fail to state a plausible claim of direct noninfringement. D.I. 2 at ¶ 67. And NS’s claim for declaratory judgment of no indirect infringement under 35 U.S.C. § 271(b) and (c) is similarly deficient, as it presents no factual allegations either. *Id.*

Due to the conclusory nature of the pleading, NS’s request for declaration of no direct or indirect infringement of VILTEPSO® should be dismissed under Rule 12(b)(6). *Accord Princeton Digital*, 2017 WL 239326, at *5; *Pilot*, 2021 WL 2188525, at *4.

D. CLAIMS IV-X SHOULD BE DISMISSED UNDER RULE 12(B)(7) FOR FAILURE TO JOIN A PARTY PURSUANT TO RULE 19

NS’s infringement claims (Claims IV-X) must be dismissed because they cannot be decided without patentee NCNP, a necessary party. Federal Rule of Civil Procedure 12(b)(7) provides for the dismissal of a complaint for “failure to join a party under Rule 19.” Fed. R. Civ. P. 12(b)(7). A Rule 19 analysis involves two steps. *See Gen. Refractories*, 500 F.3d at 312. First, the Court must determine whether the absent party is “necessary” under Rule 19(a). *Id.* Second, if a “necessary party” cannot feasibly be joined, the Court must determine whether the case should be dismissed because that party is “indispensable” under Rule 19(b). *See Lone Star Silicon Innovations LLC v. Nanya Tech.*, 925 F.3d 1225, 1236 (Fed. Cir. 2019); *A123 Sys., Inc. v. Hydro-Quebec*, 626 F.3d 1213, 1220 (Fed. Cir. 2010).

Under the first step, patentees have long been deemed “necessary” parties in patent suits. *See Delano Farms Co. v. Cal. Table Grape Comm’n*, 655 F.3d 1337, 1342 (Fed. Cir. 2011) (“It is well established that a patentee is a necessary party to an action on the patent”); *cf. Independent Wireless Tel. Co. v. Radio Corp.*, 269 U.S. 459, 466 (1926) (stating that the patent owner and exclusive licensee are both generally necessary parties in an action in equity). Here, NS recognizes that NCNP is a patentee with it on all seven asserted NS Patents, D.I. 2 at ¶¶ 30-36, making it at least a “necessary party” under Rule 19(a). *See Lone Star*, 925 F.3d at 1237 (“If AMD is the patentee, as the district court correctly concluded, then AMD’s joinder would ordinarily be required.”); *A123 Sys.*, 626 F.3d at 1217 (must “join both the exclusive licensee and the patentee in a declaratory action because the patentee is a necessary party”). The Complaint alleges that each of the NS Patents was “issued to Nippon Shinyaku and NCNP as assignees,” *see* D.I. 2 at ¶¶ 30-36, adding only that, “[b]y virtue of a license agreement with NCNP, Nippon Shinyaku holds the exclusive assertion rights for the NS Patents,” *id.* at ¶ 37. A party’s characterization of its rights in a patent as “exclusive” is not dispositive; it must be determined whether that party holds exclusionary rights by analyzing the rights conferred by agreement. *See Morrow v. Microsoft Corp.*, 499 F.3d 1332, 1340 n.7 (Fed. Cir. 2007); *cf. Pfizer, Inc. v. Elan Pharm. Research Corp.*, 812 F. Supp. 1352, 1358 (D. Del. 1993) (“[T]he Court must consider the Bayer/Pfizer Agreement to determine the standing issue.”). The license agreement NS mentions, however, is not attached to the Complaint.

Publicly available information shows that NCNP is a necessary party. NCNP filed mandatory notices and power-of-attorney documents in the USPTO on August 4, 2021, for all seven pending IPRs. *See Ali v. Carnegie Inst.*, 306 F.R.D. 20, 25 (D.D.C. 2014) (for purposes of a Rule 12(b)(7) motion, a court may consider matters outside the pleading when determining

whether Rule 19 requires that a party be joined); *Pfizer*, 812 F. Supp. at 1357-58; *see also Gustavson v. Wrigley Sales Co.*, 961 F. Supp. 2d 1100, 1113 n.1 (N.D. Cal. 2013) (district court taking notice of FDA guidance document in context of motion to dismiss, stating that “[t]he Court may take judicial notice of materials available on government agency websites”); *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014) (holding that court may take notice of matters of public record in context of motion to dismiss). In its recent filings at the USPTO, NCNP states:

Pursuant to 37 C.F.R. § 42.8(a)(2), Patent Owner National Center of Neurology and Psychiatry (“NCNP”) submits the following mandatory notices.

I. Real Parties-in-Interest (37 C.F.R. § 42.8(b)(1))

Nippon Shinyaku Co. Ltd. and NCNP are the Patent Owners and real parties-in-interest in this matter.

See Sarepta Therapeutics, Inc. v. Nippon Shinyaku Co., Ltd., IPR2021-01134, Paper No. 7 at 1 (PTAB filed Aug. 4, 2021).⁸ This indicates that NCNP retains a current interest in activities pertaining to the NS Patents.⁹ *See Pfizer*, 812 F. Supp. at 1375 (under Rule 19, “[a] patent owner should be viewed as a necessary party if it retains ‘any interest’ in the patent.”). Similarly, NCNP may be prejudiced to the extent the NS Patents are held invalid in its absence in this case. *See AI23 Sys.*, 626 F.3d at 1221 (stating that if the court were “to reinstate the action and declare the patents invalid, [the absent party] would lose all rights in its patents despite the fact that it had no opportunity to defend its interests in the litigation”). Furthermore, proceeding here without NCNP

⁸ *See also* IPR2021-01135, Paper No. 7; IPR2021-01136, Paper No. 8; IPR2021-01137, Paper No. 7; IPR2021-01138, Paper No. 7; IPR2021-01139, Paper No. 7; IPR2021-01140, Paper No. 6.

⁹ A “real party in interest” is “[a] person entitled under the substantive law to enforce the right sued on and who generally, but not necessarily, benefits from the action’s final outcome.” Black’s Law Dictionary 1232 (9th ed. 2009).

would subject Sarepta to substantial risk of exposure to multiple liability, as NCNP could potentially sue Sarepta separately for infringement of the same patents. *See* Fed. R. Civ. P. 19(a)(1)(B)(ii); *Independent Wireless*, 269 U.S. at 468 (“The presence of the owner of the patent as a party is indispensable . . . in most cases to enable the alleged infringer to respond in one action to all claims of infringement for his act, and thus either to defeat all claims in the one action, or by satisfying one adverse decree to bar all subsequent actions.”).

In view of this information from the USPTO proceedings in which NCNP describes itself as a “real party-in-interest,” NS has failed to plead in the Complaint why NCNP, as a patentee on the asserted NS patents, is not a “necessary” party to this suit. And if a party like NCNP is necessary under Rule 19(a), it must be joined if feasible. *See Lone Star*, 925 F.3d at 1237 (“If AMD is the patentee, as the district court correctly concluded, then AMD’s joinder would ordinarily be required.”); *cf. Carnegie Inst. of Wash.*, 306 F.R.D at 25-26 (“Due to UMass’s ownership interest in the patents . . . the Court finds that UMass is a required party that must be joined if feasible.”). Yet NS’s Complaint fails to state, as it must “(1) the name, if known, of any person who is required to be joined if feasible but is not joined; and (2) the reasons for not joining that person.” Fed. R. Civ. P. 19(c) (emphasis added); *cf. Lone Star*, 925 F.3d at 1238 (“Regardless, Rule 19 is mandatory and so it applies whether a defendant invokes Rule 12(b)(1), (6), (7), or none of the above.”) (emphasis added). NS had the pleading burden under Rule 19(c) but made no attempt to meet that burden. *See generally* D.I. 2 at ¶¶ 28-37.

In the second step of a Rule 19 analysis, the court must determine whether the case should proceed without the absent party or whether the party is “indispensable” such that the case must be dismissed. *See A123 Sys.*, 626 F.3d at 1220. Based on NCNP’s admitted status as a patentee, it appears that NCNP would also be indispensable to the suit under the legal test of Rule 19(b):

First, *prejudice* results because Sarepta should be permitted “to respond in one action to all claims of infringement,” *Independent Wireless*, 269 U.S. at 468, and, conversely, if NCNP’s patents are held invalid, it “would lose all rights in its patents despite the fact that it had no opportunity to defend its interests in the litigation,” *A123 Sys.*, 626 F.3d at 1221. *See also Carnegie Inst. of Wash.*, 306 F.R.D. at 26 (recognizing that the evaluation of the first Rule 19(b) factor overlaps considerably with the Rule 19(a) analysis).

Second, *mitigation* is unlikely, since there are no measures that might be taken by the Court to reduce the above prejudice were the case to proceed.

And third, the *adequacy of judgment* weighs in favor of finding NCNP to be indispensable because nonjoinder would create a risk of multiple lawsuits and of inconsistent relief. *See A123 Sys.*, 626 F.3d at 1222.

V. CONCLUSION

For the foregoing reasons, the Court should grant Sarepta’s Rule 12 motion.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

OF COUNSEL:

Charles E. Lipsey
J. Derek McCorquindale
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
1875 Explorer Street, Suite 800
Reston, VA 20190
(571) 203-2755

Michael J. Flibbert
Aaron Gleaton Clay
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001
(202) 408-4210

Jack B. Blumenfeld (#1014)
Megan E. Dellinger (#5739)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
mdellinger@morrisnichols.com

*Attorneys for Defendant Sarepta
Therapeutics, Inc.*

Alissa K. Lipton
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
Two Seaport Lane
Boston, MA 02210
(617) 646-1600

September 3, 2021

CERTIFICATE OF SERVICE

I hereby certify that on September 10, 2021, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on September 10, 2021, upon the following in the manner indicated:

Amy M. Dudash, Esquire
MORGAN, LEWIS & BOCKIUS LLP
1201 North Market Street, Suite 2201
Wilmington, DE 19801
Attorneys for Plaintiff

VIA ELECTRONIC MAIL

Amanda S. Williamson, Esquire
Christopher J. Betti, Esquire
Krista Vink Venegas, Esquire
Maria E. Doukas, Esquire
Michael T. Sikora, Esquire
MORGAN, LEWIS & BOCKIUS LLP
110 North Wacker Drive, Suite 2800
Chicago, IL 60606
Attorneys for Plaintiff

VIA ELECTRONIC MAIL

Jitsuro Morishita, Esquire
MORGAN, LEWIS & BOCKIUS LLP
16F, Marunouchi Building,
2-4-1 Marunouchi, Chiyoda-ku
Tokyo, 100-6316 Japan
Attorneys for Plaintiff

VIA ELECTRONIC MAIL

/s/ Megan E. Dellinger

Megan E. Dellinger (#5739)